PUBLIC COMMENT

In Response to HHS Request for Information — "Chronic Disease of Addiction"

Agency: U.S. Department of Health and Human Services (HHS)

Docket / FR Doc: FR Doc. 2026-11602; 91 FR 35221 (June 10, 2026)

Submission: REPORTSCLEARANCEOFFICER@ahrq.hhs.gov — subject line "Great American Recovery"

Comment deadline: July 5, 2026

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Attachments: (1) Exhibit H — Procedural Record (VA/DoD CPG 2017 and Evidence Synthesis Report excerpts); (2) Evidence Exhibits A–D; (3) FOIA Initial Agency Decision, Request No. 25-25897-F (redacted) — see manifest, Section VI

I. Introduction and Purpose

This comment respectfully urges HHS to adopt a consistent, transparent standard of **evidence incorporation** across its addiction-related programs and policies — applying the same less-restrictive, continuity-of-care approach to decisions affecting access to controlled substances that the Department's own clinical guidelines already endorse.

In one sentence: the 2017 VA/DoD opioid-guideline development process illustrates a procedural pattern that should be guarded against in current and future federal actions affecting treatment access — patient input was solicited, yet its disposition is not visible in the published guideline; the underlying tapering evidence was internally graded "Very low quality"; and system-wide dose reduction proceeded without a built-in outcome-monitoring component, with adverse mortality associations later identified by external researchers rather than by contemporaneous program surveillance.

The comment is offered in an **advocacy, non-commercial** capacity. It is focused narrowly on *methodological transparency*, *guideline-development processes*, *and how evidence is weighed and incorporated*. It makes **no** allegation of negligence, misconduct, or intentional wrongdoing by any individual or institution. Where the Department's own materials are quoted, they are quoted to illustrate the standard the Department has already articulated for itself, and to recommend that the same standard be applied consistently going forward.

The recommendations below respond to Questions 2, 3, and 5 of the RFI in the four-part format the notice requests (Title; Type of activity; Description; Statutory authority). Where additional record detail supports an idea, it is provided in a separate "Supporting record" note so that each Description remains within the RFI's requested three-to-five-sentence length. Consistent with the RFI's instruction that commenters "cite all sources and data sets with links," supporting citations are collected in Section V and referenced inline.

Framing note on evidence standards. As general background — not as a claim that this RFI itself triggers rulemaking duties — the principles reflected in the Administrative Procedure Act, that agencies consider significant evidence placed before them (5 U.S.C. § 553(c)) and that policy choices be supported by a rational connection to the record rather than being arbitrary and capricious (5 U.S.C. § 706(2)(A)), are useful touchstones for the kind of transparent, evidence-anchored process this comment recommends.

II. Response to Question 2

Question 2 asks: using existing funding, what policies or changes to federal programs might improve outcomes in substance-use and co-occurring-disorder prevention, treatment, and recovery? The following ideas are drawn from the Department's own clinical evidence base.

Policy Idea 2.1 — Require Validated Continuity-of-Care Protocols Before Any Program Reduces or Removes Access to an Existing Therapy

Title: Continuity-of-Care Safeguard for Discontinuation and Supply-Reduction Measures

Type of activity: Best-practices guidance and grant condition (no new appropriation required)

Description: HHS should condition relevant grants and guidance so that any federally supported program that discontinues, tapers, or restricts access to an existing therapy first has a validated transition and monitoring protocol in place. This mirrors the Department's own clinical standard: the VA/DoD Clinical Practice Guideline for Opioid Therapy (2017) advises, in the note to Recommendation 14, that "Abrupt discontinuation should be avoided unless required for immediate safety concerns," and Recommendation 15 acknowledges that "There is insufficient evidence to recommend for or against specific tapering strategies and schedules." The accompanying Evidence Synthesis Report — prepared by the evidence contractor, The Lewin Group / Center for Comparative Effectiveness Research — states that "Both studies received a Very low quality rating for their outcomes due to serious study limitations and imprecision in their findings based on the GRADE criteria" (Key Question 9, p. 323). Requiring a documented safety protocol before access is reduced applies that acknowledged uncertainty consistently and protects patients during transitions. Published analyses associate abrupt cessation with elevated mortality risk (see Section V, Sources 3–4), which underscores the value of a continuity safeguard.

Statutory authority: 42 U.S.C. § 290aa (SAMHSA authority to identify and disseminate evidence-based best practices for substance-use and mental-health programs).

Supporting record: The guideline's evidence review identified only two studies for the tapering key question — Wang et al. (2011), a prospective study of pain sensitivity in chronic low-back-pain patients, and Nomura et al. (2011), a randomized controlled trial of fentanyl conversion methods in cancer-pain patients — neither of which directly addressed the chronic-pain population to which system-wide tapering was subsequently applied (Attachment 1, Exhibit H, Evidence Synthesis Report p. 323). The evidentiary finding was retained in the 2022 update (Version 4.0): "There is insufficient evidence to recommend for or against any specific tapering strategies. We suggest a collaborative, patient-centered approach to opioid tapering" (2022 CPG, p. 34).

Policy Idea 2.2 — Prefer Less-Restrictive Risk-Mitigation Tools Consistent With Existing Agency Practice

Title: Proportionate, Least-Restrictive Risk-Mitigation Standard

Type of activity: Guidance / interagency policy alignment (existing funding)

Description: HHS should encourage that known pharmacological risks be managed, where feasible, through the least-restrictive effective tool — clinical warnings, prescriber education, monitoring, and guidelines — reserving access-removal for situations where less-restrictive measures are shown to be inadequate. The Department already manages serious, quantified risks in exactly this way: the VA/DoD guideline reports that co-prescribing opioids with benzodiazepines carried an odds ratio for

drug-related death of 14.92 (95% CI 7.00–31.77), a documented near-15-fold risk that the guideline addresses through clinical warnings and prescribing guidance rather than by removing access to either medication class. Applying access-removal to comparably situated risks, while a quantified 15-fold risk is managed through warnings, would apply a disparate and disproportionate regulatory standard. A consistent proportionality principle promotes transparency in how the Department incorporates risk evidence. This idea complements, rather than replaces, the safety protocols in Idea 2.1.

Statutory authority: 42 U.S.C. § 290aa (SAMHSA best-practices authority); and, where a scheduling determination is contemplated by a sister agency, 21 U.S.C. § 811(c) (requiring consideration of the enumerated scientific and public-health factors), which HHS's scientific and medical evaluation informs.

III. Response to Question 3

Question 3 asks how federal policies and programs can be improved to mitigate the stigma against Americans seeking addiction treatment and recovery, consistent with E.O. 14379's call to "increase awareness of the disease of addiction" and "foster a culture that celebrates recovery."

Policy Idea 3.1 — Patient-Education and Shared-Decision Standards That Reduce Stigma-Driven Involuntary Discontinuation

Title: Patient Education, Alternatives, and Monitoring Standard

Type of activity: Best-practices guidance (existing funding)

Description: Stigma can contribute to patients being abruptly or involuntarily removed from therapy without adequate explanation or transition support. The VA/DoD guideline's patient-focused guidance calls on clinicians to educate patients regarding the treatment plan, alternative treatment options, and monitoring, and to "provide seamless transitions" so that patients "should not have to encounter abrupt changes in treatment regimens." HHS should promote these shared-decision and continuity standards across its funded programs so that awareness and dignity — not stigma — drive treatment transitions. This directly advances E.O. 14379's culture-of-recovery goal by keeping patients engaged in care rather than disengaged by abrupt change.

Statutory authority: 42 U.S.C. § 290aa (SAMHSA authority to disseminate best practices, including patient-education and shared-decision standards).

Supporting record: The FOIA procedural record (Request 25-25897-F; Attachment 3) confirms that a VA-convened patient focus group informed the 2017 guideline development process; the VA's Director of Evidence Based Practice stated that subject-matter experts "used the information from our systematic evidence review and our patient focus group to develop the guideline recommendations." The published guideline, however, contains no visible disposition of that input: it includes no specific tapering-safety protocol, and Recommendation 15 concedes insufficient evidence on the very cessation strategies at issue. When the disposition of solicited input is not visible, patients may reasonably conclude that their stated medical needs carry no weight — a dynamic that deepens the very treatment-seeking stigma the RFI seeks to address. Publishing a disposition of such input, as recommended here, would make its incorporation (or reasoned non-incorporation) visible.

Policy Idea 3.2 — Avoid Policies That Foreseeably Displace Patients Toward the Illicit Market

Title: Displacement-Awareness Review for Access-Restricting Measures

Type of activity: Policy-review guidance (existing funding)

Description: When a legal or regulated option is removed, some individuals may transition to the unregulated illicit market, which can worsen rather than reduce harm — an outcome that also deepens stigma by pushing use underground. A 2022 epidemiological dissertation examining state-level bans of a kratom-derived compound found, using an interrupted-time-series design, that opioid-overdose mortality continued to rise (and in several states accelerated) after bans took effect, and the author concluded the prohibition policies did not achieve their stated public-health goals (see Section V, Source 5). HHS should encourage a brief displacement-awareness review before endorsing access-restricting measures, so that stigma-reduction goals are not undercut by unintended migration to riskier supply.

Statutory authority: 42 U.S.C. § 290aa (SAMHSA best-practices and policy-guidance authority).

IV. Response to Question 5

Question 5 asks how HHS can strengthen its ability to evaluate program effectiveness, and how it can leverage data modernization, advanced analytics, and emerging technologies to enable performance measurement on a real-time or continuing basis. This is the most direct fit for the methodological-transparency focus of this comment.

Policy Idea 5.1 — Pre/Post Interrupted-Time-Series Evaluation of Cessation and Supply-Restriction Measures

Title: Standardized Pre/Post Evaluation Protocol for Access-Affecting Policies

Type of activity: Evaluation methodology / data-modernization operational standard (existing funding)

Description: HHS should adopt a standardized interrupted-time-series (ITS) evaluation protocol for any policy that changes access to a therapy, comparing outcome trends before and after implementation against a comparison group. This is the same transparent, replicable method used in the peer-reviewed and dissertation literature cited in Section V, and it lets the Department detect when a well-intentioned measure is associated with worsening outcomes rather than assuming benefit. The evaluation should specify outcome measures, comparison groups, and analysis windows in advance to preserve methodological transparency. Building the protocol into program design at the outset — rather than reconstructing it after the fact — strengthens evidence incorporation and accountability.

Statutory authority: 42 U.S.C. § 242k (National Center for Health Statistics data-collection and health-statistics authority), supporting standardized outcome measurement and evaluation.

Supporting record: The 2017 guideline record before us reflects no built-in data-collection or monitoring component for patients who were tapered or discontinued. The adverse associations were identified years later by external researchers — Oliva et al. (BMJ 2020) and Tibbitts & Cowan (NBER Working Paper 29139, 2021) — rather than by contemporaneous program surveillance, illustrating precisely the evaluation gap this idea would close. Relatedly, the evidence review's search-term record (Attachment 2, Exhibit C) shows how outcome-coverage gaps can arise at the literature-search stage; publishing and auditing search strategies in advance serves the same evaluation goal.

Policy Idea 5.2 — Near-Real-Time Surveillance Linkage to Flag Adverse Trends After Policy Changes

Title: Surveillance-Linked Early-Warning Capability for Program Evaluation

Type of activity: Data modernization / advanced analytics (existing infrastructure)

Description: HHS should link program-evaluation dashboards to existing near-real-time public-health situational-awareness and mortality data so that increases in overdose or suicide following a program or policy change are surfaced quickly rather than years later. Existing analyses associate certain cessation and supply-restriction measures with elevated overdose-and-suicide risk (see Section V, Sources 3–4); a monitoring capability that flags such divergences supports timely, evidence-based course correction. Advanced analytics — including anomaly detection and, where validated, machine-learning models — can be applied to these linked feeds to enable continuing performance measurement as the RFI envisions. The capability leverages infrastructure the Department already operates.

Statutory authority: 42 U.S.C. § 300hh-31 (near-real-time electronic nationwide public-health situational-awareness network); and 42 U.S.C. § 242k (NCHS health-statistics and mortality data).

V. Supporting Sources and Data (with Links)

Per the RFI's request that commenters cite sources with links, the following materials support the ideas above. Government-authored guideline text is quoted directly; copyrighted academic sources are paraphrased with citations. Sources are numbered 1–6; attached exhibit files retain their internal letter designations (see manifest, Section VI).

1. VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain, Version 3.0 (Feb. 2017), and VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain, Version 4.0 (2022). U.S. Government works. The 2017 guideline's Recommendation 14 note ("Abrupt discontinuation should be avoided unless required for immediate safety concerns"), Recommendation 15 note ("There is insufficient evidence to recommend for or against specific tapering strategies and schedules"), patient-education/continuity provisions, and the opioid–benzodiazepine drug-related-death odds ratio of 14.92 (95% CI 7.00–31.77) are excerpted in Attachment 1 (Exhibit H). The evidentiary finding is retained in the 2022 update: "There is insufficient evidence to recommend for or against any specific tapering strategies" (2022 CPG, p. 34). 2017 version available via the Federal Depository Library Program: purl.fdlp.gov/GPO/gpo111953. 2022 version: https://www.healthquality.va.gov/guidelines/Pain/cot/

2. VA/DoD COT CPG Evidence Synthesis Report (The Lewin Group / Center for Comparative Effectiveness Research, 2017), Key Question 9 — "Both studies received a Very low quality rating for their outcomes due to serious study limitations and imprecision in their findings based on the GRADE criteria" (p. 323). Excerpt included in Attachment 1 (Exhibit H).

3. Oliva, E. M., et al. (2020). "Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans." BMJ, 368, m283. Reported an estimated hazard ratio of approximately 6.77 for overdose or suicide death among patients whose opioid treatment was stopped after more than 400 days, relative to those who continued. Framed as an association, not causation. Table excerpt in Attachment 2 (Exhibit A). https://www.bmj.com/content/368/bmj.m283

4. Tibbitts, J. C., & Cowan, B. W. (2021). "The Opioid Safety Initiative and Veteran Suicides." NBER Working Paper No. 29139. Estimates an association between the 2013 Opioid Safety Initiative and a divergence in veteran suicide trends relative to a civilian comparison group, concentrated among rural veterans. Presented as associational. Figure excerpt in Attachment 2 (Exhibit B). https://www.nber.org/papers/w29139

5. Blair, L. (2022). Investigating the relationships between socioeconomic status, kratom legislation, and the COVID-19 pandemic on opioid overdose mortality in the United States (doctoral dissertation, University of Louisville). Paraphrased: using an interrupted-time-series design, found opioid-overdose mortality continued to rise — and in several states accelerated — after state-level bans, and concluded the bans did not achieve their stated public-health goals; the author notes causation cannot be established. Excerpts in Attachment 2 (Exhibit D). https://ir.library.louisville.edu/etd/

6. FOIA procedural record, Request No. 25-25897-F (Department of Veterans Affairs). The VA's Initial Agency Decision (June 26, 2025; redacted copy at Attachment 3) confirms that The Lewin Group served as the CPG development contractor for the relevant period, that a patient focus group informed the guideline process, and identifies four responsive documents totaling 578 pages, including the Opioid CPG Final Evidence Report (2016) and the VA/DoD CPG Opioid Therapy for Chronic Pain v.3 (2017) excerpted in Attachment 1 (Exhibit H); the evidence-review search-term record is reproduced in Attachment 2 (Exhibit C). The record is publicly retrievable via the Internet Archive using the identifier 25-25897-F, and the full document set is available from the VA FOIA office under the same request number.

VI. Attachment Manifest, Verification, and Signature

Attachment 1: Exhibit H — Procedural Record: excerpts from the VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain (2017) and the associated Evidence Synthesis Report (The Lewin Group), submitted to illustrate the Department's stated evidence standard.

Attachment 2: Evidence Exhibits A–D — Exhibit A: Oliva et al. (2020), BMJ table excerpt (Source 3); Exhibit B: Tibbitts & Cowan (2021), NBER Working Paper 29139 figure excerpt (Source 4); Exhibit C: evidence-review search-term record from the guideline development process (Source 6); Exhibit D: Blair (2022) state-level ban analysis excerpts (Source 5).

Attachment 3: FOIA Initial Agency Decision, Request No. 25-25897-F (VHA FOIA Office, June 26, 2025), submitted as proof of the scope and provenance of the procedural record. The decision confirms The Lewin Group as the CPG development contractor, confirms the patient focus group's role in the guideline process, and identifies the four responsive documents (578 pages) from which Attachments 1 and 2 are excerpted. Requester-identifying information and individual names/email addresses have been redacted by the submitter; the agency's own (b)(5) and (b)(6) withholdings are as stated in the decision.

Verification: The underlying FOIA procedural record (Request 25-25897-F) is referenced throughout this comment. The full document set is available from the VA FOIA office; excerpts are attached as Exhibit H. The agency may verify the record by referencing FOIA Request 25-25897-F.

Respectfully submitted,

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Submitted in response to FR Doc. 2026-11602 (91 FR 35221) — subject line "Great American Recovery."